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Dental Mercury Regulations, 310 CMR 73.00
Public Comments Summary
January 2006

Submitters: Massachusetts Dental Society, Environmental League of Massachusetts, joint letter from Clean Water Action, Healthcare Without Harm, Mercury Policy Project, and the National Wildlife Federation, Peter Berglund (Metropolitan Council Environmental Services, Industrial Waste and Pollution – Minneapolis/St. Paul)

1. **Efficiency of amalgam separators: require 95%, 98% or 99% removal efficiency.** One commenter recommended that MassDEP adhere to the requirement for 95% amalgam particulate removal efficiency rather than the proposed 98% because ISO protocol 11143 cannot, according to the commenter, consistently validate removal efficiency above 95%. Two commenters supported the requirement for 98% removal efficiency.

Response: In its final regulations, MassDEP is maintaining its proposed requirement for new certifications to comply with the 98% removal efficiency for amalgam separators. The final regulations also define in greater detail the requirement for 98% removal efficiency, to establish that it is based on the average test results under empty and simulated full conditions (using ISO protocol 11143). This approach has been used by several other jurisdictions as the basis for establishing a required minimum removal efficiency of 98%.

2. **Should all new amalgam separators be required to meet the same 98% removal efficiency?** One commenter stated that all dental facilities should be required to install amalgam separators with 95% removal efficiency. Other commenters stated that the 98% removal efficiency standard should apply to all dentists. These commenters stated that, for dental offices with space constraints, compact separators currently exist on the market that achieve 98% removal efficiency.

Response: MassDEP did not receive comments indicating that space constraints can preclude a dental facility from installing an amalgam separator with 98% or greater amalgam removal efficiency. MassDEP is therefore requiring that all new amalgam separators meet a minimum 98% efficiency.

3. **Life expectancy of amalgam separators.** One commenter stated that it believed a well-maintained amalgam separator could be expected to operate at maximum efficiency for at least ten years, and probably more. According to this commenter, some dental offices in Massachusetts

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have had amalgam separators for more than five years that are still operational. Another commenter opposed grandfathering the 95% units allowed under the voluntary program, citing a study (submitted with the comment) indicating that separator performance degrades over time.

Response: In its final rule, MassDEP is grandfathering amalgam separators installed under the voluntary program, allowing their continued use as long as they still achieve a 95% or better dental amalgam removal efficiency. See “Approved Amalgam Separator” definition at 310 CMR 73.02.

- 4. Should dentists that do not place amalgam-containing mercury fillings be exempt from regulation?** One commenter stated that pediatric dentists that do not place amalgam fillings but occasionally remove them should be excluded from these regulations. The commenter recommended that MassDEP require a statement from pediatric dentists certifying that they do not place amalgam fillings but occasionally remove them, thereby excluding such pediatric dentists from these regulations. Other commenters stated that the cost of purchasing, installing and maintaining an amalgam separator is not so onerous as to warrant exempting any class of dentist if they dealing with amalgam in any way.

Response: Dental facilities that do not generate or discharge wastewater from amalgam-related processes or facilities that use mercury free filling material and do not place or remove amalgam may submit to MassDEP a statement of non-applicability pursuant to 310 CMR 70.03(1)(c). The final regulation also exempts dentists in certain specialty practices that generate insignificant quantities of mercury amalgam waste (incidental to their practice), as proposed.

- 5. Criteria for acceptability of amalgam separators and reliability of ISO protocol test data generated by separator manufacturers.** Commenter questioned the reliability of “self-generated” data and why MassDEP would accept “manufacturer generated data.” What penalties would a dental practice face if they installed an amalgam separator based on the manufacturer’s claims that turn out to be false?

Response: The regulation makes dental facilities responsible for purchasing amalgam separators that meet the established performance standards, but recognizes that testing to ascertain removal efficiency is performed by analytical laboratories and paid for by the manufacturers. MassDEP assumes that these purchasing decisions will be based on information provided by the manufacturers (and/or separator vendors), but recommends that dentists review the information available about the unit they are considering purchasing, to ensure that it meets the applicable performance criteria.

- 6. ISO protocol 11143.** Which version of the ISO 11143 protocol will be required for amalgam separators?

Response: The final version of the regulations does not specify a particular version of the ISO 11143 protocol. MassDEP will accept testing conducted in accordance with the current version of the ISO 11143 protocol, but does not want to lock in the current version that may be improved in the future. Amalgam separator models will need to be tested in accordance with the version of the ISO protocol that is in effect at the time the test is conducted.

- 7. Testing Certification Requirement.** MassDEP should include a requirement for a third party certification that ensures that new separator models are tested at laboratories that follow appropriate Quality Assurance and Quality Control procedures, and thereby prevent unqualified laboratories from providing invalid amalgam separator testing results.

Response: In several other states (Vermont, New Hampshire and Minnesota), dentists have attempted to install “home-made” amalgam separators that were not tested by qualified labs. To guard against testing done by labs that do not follow industry-standard quality assurance and quality control procedures, the definition of “Approved Amalgam Separator” has been revised to require that “Such removal efficiency shall be determined on the basis of test data generated by a professional laboratory qualified to perform the following analytical methods:(a) ISO protocol 11143, using average test results under empty and simulated full conditions; or (b) an equivalent method that meets DEP approved quality assurance and quality control criteria.

8. **Alternatives to ISO Protocol 11143.** One commenter supported MassDEP’s strategy of maintaining flexibility in the regulation to allow for additional testing methods beyond the ISO protocol 11143.

Response. MassDEP will retain flexibility in the regulation to allow for additional methods beyond the ISO protocol 11143.

9. **Common Carrier.** Commenter requested clarification that “common carrier” (hauler for waste amalgam to recycler) includes UPS, Fed Ex, Postal Service, etc.

Response: The term “common carrier” includes (but is not limited) to the carriers mentioned by the commenter.

10. **Recertification.** Will MassDEP notify dentists that they must recertify their amalgam separator?

Response: MassDEP will notify dentists in advance of their recertification deadline.

11. **Frequency of Recertification** Commenter suggested that recertification should not be every five years as proposed, but when the dental office installs a replacement amalgam separator or at ten year intervals at a minimum. Another commenter suggested recertifications as frequently as every year, but no less than every five years so MassDEP can effectively monitor compliance.

Response: MassDEP believes the proposed five-year recertification period is an appropriate interval and retained this language in the final rules. MassDEP may reevaluate this certification period in the future.

12. **Patient Notification:** Commenter urged MassDEP to require dentists to provide written notice to patients about various types of fillings available, including the environmental and health impacts of different filling types.

Response: This comment is beyond the scope of MassDEP’s regulatory and statutory authority, and has not been addressed in the final regulation.

13. **Dental Insurance.** Commenter stated that all state dental insurance contracts should include coverage for non-mercury fillings that is equal to or better than that for mercury fillings.

Response: This comment is beyond the scope of MassDEP’s regulatory and statutory authority, and has not been addressed in the final regulation.

14. **Recordkeeping.** MassDEP should require that certification records be kept for the life of the amalgam separator.

Response: MassDEP retained the five-year recordkeeping requirement because it ensures that records will be available to support certifications filed every five years.

15. **Employee training.** Require that all employees who handle amalgam or waste amalgam be trained in procedures to follow to insure compliance with regulation.

Response: At least one employee needs to be trained about requirements that ensure proper operation and maintenance of the amalgam separator and the regulation's operational standards. The final regulation also specifies that all employees who handle amalgam waste must be informed about these requirements. This should provide dental facilities with flexibility to make information and training applicable to staff job responsibilities. See 310 CMR 73.07(1)(g).

16. **One-time cleanouts.** MassDEP should add a requirement for a one-time cleanout of office pipes and management of collected "washout" as hazardous waste.

Response: MassDEP has not assessed the cost and impacts of such a requirement, and has therefore not included it in the final regulation.

17. **Septic Tanks.** MassDEP should require mercury testing of contents of septic tanks that have received dental waste before septage is hauled away.

Response: Title V of the State Sanitary Code (310 CMR 15.000) addresses this issue by prohibiting the discharge of "medical waste", which is defined to include dental waste, into septic systems. MassDEP works with local Boards of Health to enforce this provision.

18. **Line cleaners.** One commenter stated that the proposed language accurately describes the types of line cleaners and disinfectants that should be used to minimize releases of dissolved mercury. Another suggested that the upper pH limit should be increased to 9.0 to give dentists a broader range of product choices.

Response. The pH range was expanded from 6.5-8.5 to 6.5-9.0 to give dentists a broader selection of line cleaners. This change is not believed to pose an adverse environmental effect.

19. **Recycling mandate.** Instead of mandating mercury recycling, commenter suggested that MassDEP might instead want to require lawful amalgam disposal so that it is "taken out of circulation" and not reintroduced into mercury-added products.

Response: The final rule maintains the proposed recycling requirement. At this time, recycling is the primary waste management option for generators with hazardous waste containing mercury, mainly due to federal hazardous waste disposal rules, which restrict land disposal of mercury wastes. Recycling reduces the need to use "virgin" mercury. Also, currently, there is no national strategy for retiring and sequestering excess mercury.

20. **Definition of Amalgam Separator.** Insert the words "the vacuum system, or" immediately after "passing through" to more accurately define an Amalgam Separator.

Response: The final regulation incorporates this suggestion. See 310 CMR 73.02, Definitions (Amalgam Separator)

21. **Listing Dentists in Certifications:** Commenter questioned why the names of all dentists practicing at the dental office are important in relation to these regulations.

Response: MassDEP initially required this information in order to establish the participation rate in its voluntary program in 2004 and 2005. The final regulation places clear responsibility for compliance on the owners and operators of dental facilities, rather than individual dentists. Therefore, the requirement to list each dentist at a dental facility has been removed.

20. **Similar amalgam separator requirements.** The requirements at 310 CMR 73.04(1)(d) and (e) appear to be redundant.

Response: MassDEP agrees; 73.04(d) has been deleted and 73.04(e)-(g) renumbered as (d)-(f).

21. **Should MassDEP require that all certifications be submitted electronically?** One commenter stated that dentists without access to the web or those using a Macintosh operating system, or those using a modem should not have to pay a higher fee. Another commenter said that if MassDEP uses needs additional resources to process atypical submittals, then it should assess a limited fee.

Response: While many of the technical problems that arose with early electronic filings by dentists in the early stages of the voluntary program have been resolved, MassDEP appreciates that there may be some dentists who are not comfortable with this method of filing required certifications. Therefore, the final rules will allow the submittal of paper certifications. However, MassDEP plans to encourage dental practices to file their certifications on-line, in order to reduce paperwork and agency administrative costs.